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PEDIATRIC THEME

Steps to transform a necessity into a validated and useful screening tool for early detection of developmental problems in Mexican children

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KEYWORDS

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Abstract A screening test is an instrument whose primary function is to identify individuals with a probable disease among an apparently healthy population, establishing risk or suspicion of a disease. Caution must be taken when using a screening tool in order to avoid unrealistic measurements, delaying an intervention for those who may benefit from it.

Before introducing a screening test into clinical practice, it is necessary to certify the presence of some characteristics making its worth useful. This “certification” process is called validation. The main objective of this paper is to describe the different steps that must be taken, from the identification of a need for early detection through the generation of a validated and reliable screening tool using, as an example, the process for the modified version of the Child Development Evaluation Test (CDE or Prueba EDI) in Mexico.

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PALABRAS CLAVE

Prueba de tamiz;
Validación;
Prueba EDI;
Desarrollo infantil

Pasos para transformar una necesidad en una herramienta válida y útil para la detección oportuna de problemas en el desarrollo infantil en México

Resumen Una prueba de tamiz es una herramienta cuya función es identificar individuos presuntamente enfermos en una población aparentemente sana al establecer el riesgo o sospecha de un problema de desarrollo. Debe tenerse precaución y ser muy cuidadoso al utilizar un instrumento de este tipo, por el riesgo de efectuar mediciones que no coincidan con la realidad y retrasar una intervención a quien lo requiere.

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Antes de incorporar una prueba de este tipo como parte de la práctica clínica rutinaria, es necesario certificar que posee ciertas características que hacen meritoria su utilización. A este proceso de certificación se le denomina validación. El objetivo de este artículo fue describir los diferentes pasos que se llevaron a cabo desde la identificación de una necesidad de detección hasta la generación de una prueba de tamiz validada y confiable, utilizando como ejemplo el proceso del desarrollo de la versión modificada de la prueba Evaluación del Desarrollo Infantil (EDI) en México.

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1. Introduction

The construction of a solid foundation for healthy development during the first years of life is a fundamental requirement for individual well-being and economic productivity, successful communities and harmonious civil societies.¹ The architecture of the developing brain is constructed through a process that starts before birth, continues into adulthood and is established as a base, either strong or fragile, for health, learning and subsequent behavior.²

During the first 5 years of life there is a succession of sensitive periods, each related to the formation of circuits associated with specific abilities. Thus, brain functions have a critical period of maximum potential of development in concert with age. The level of development reached depends on the interaction of genes and early experiences.³ Based on the above, the concept of early childhood development (ECD) emerged, which covers from pregnancy and up to 6 years of age, and is a *process of change in which the child learns to master always more complex levels of movement, thinking, feelings and relations with others*. It occurs when the child interacts with people, objects, and other stimuli in the biophysical and social environment and learns from them.⁴

While the maturing brain specializes in taking on increasingly complex roles, it also becomes less able to reorganize and adapt to new challenges. Once the circuit has installed itself, it will stabilize with age, making its later alteration difficult. Although the *windows of opportunity* may remain open for many years, modifying behavior or constructing new skills on top of the brain circuits that were not properly installed when they were formed for the first time requires too much work. Additionally, greater amounts of metabolic energy are required to compensate for function of circuits that do not work as expected.⁵ Doing things correctly the first time rather than waiting and trying to correct them later is less expensive both for individuals as well as for society in general.² For this reason the correct formation of these circuits should be monitored.

Evaluation of childhood development is a process geared towards knowing and quantifying the level of maturity reached by a child compared with his/her age group,⁶ which allows to identify changes and establish an individualized profile about the strengths and weaknesses of the different domains evaluated. Early detection of developmental problems is of utmost importance for the wellbeing of children and their families because it allows achieving a timely diagnosis and treatment⁷ and implement actions within the win-

dows of opportunity to avoid consolidation of inadequate circuits and allow their reorganization in an optimal fashion. These actions allow for children to develop increasingly complex skills commensurate with their age and thus to achieve their full potential.

The clinical judgment of medical personnel is not sufficient for carrying out this evaluation and identifying patients with developmental delay. Hence, the importance of using standardized tools to detect these patients.⁸ A screening test is a tool that has as its function to identify presumably ill individuals in an apparently healthy population by establishing a risk of suspicion of a developmental problem. One must act cautiously when using an instrument because of the risk of assessing measurements that do not coincide with reality and delay an intervention in those who do require it.

Before a test of this type is incorporated as part of routine clinical practice it is necessary to certify that it has certain characteristics that make its use worthwhile. This *certification* process is called test validation.⁹ There are various processes that have been considered as validation without actually being so. The most common is to do only translations, to only carry out tests of concordance or correlation with the results of measurements with other tools or carry out only tests of concordance between different evaluators.¹⁰

The objective of this article was to describe the steps that have been carried out for the validation of screening tests (Table 1), using as an example the process of development of the modified version, validation and evaluation in the field of the CDE test. These steps should answer a series of questions.

- Are there tests that reliably quantify what one desires to measure?

The scale to be used should be the best available. For this, it is important to first analyze if there is an instrument that meets the objective desired.¹⁰ In the case of screening tests for childhood development in Mexico, given the interest of having a valid tool for timely detection, a systematic review was done based on the information available in databases and search engines of scientific publications.¹¹ There was no information found in the scientific literature on any screening test validated in Mexico. On the other hand, the tests available in America had deficiencies or different characteristics, which did not make them the most adequate for their implementation in Mexico. As part of the NOM-031-

Table 1 Description of the characteristics or attributes that warrant use of a screening test and the corresponding scale validation process*

Characteristic or attribute of the test	Evaluation process	Expected result
The existing reality is adequately represented by the scale	Validity of appearance	The test measures what should be measured
The scale reflects the structure of domains or factors representing the content to be measured	Validity of content/construct	The test does not measure factors or domains not related to the syndrome/disease
The scale works similarly to other instruments to measure previously validated responses	Validity of criteria	The scale functions similar to other instruments
The scale functions well under different conditions	Test-retest reliability or evaluator	The scale functions well when applied under different condition or when applied by different persons

*A.R. Feinstein (Ref. 9).

SSA1-1999, for child health care,¹² item 9.6.1 specifies that evaluation of the psychomotor development of the child should be done each time the child presents for consultation for monitoring nutrition and growth status, using as a reference of normality of behaviors specified in Appendix F of the same document. There was no available information found on the values of the tests contained in this Appendix (sensitivity/specificity) nor of apparent process of validation or of criteria. In addition, as result of the test, it is only reported if the child was identified as having signs of alarm. Due to these data it was concluded that *“there is no agreement on how to evaluate the physical, cognitive, social and emotional development of children in Mexico. The data used to measure them are the enrollment of boys and girls in preschool education or their registration in child care programs”*.⁴

- If there are plans to design a new tool, what clinical functions should be met and how would it be structured?

The tool that would be required in Mexico should meet the following clinical functions:

- a) Qualitative characterization of the level of development of the children. Identification of changes over time that will enable interventions appropriate to the needs of children
- b) Serve as a basis for a management guideline.

In the absence of evidence that meets these functions, the members of the General Directorate of the Opportunities Program (today PROSPERA) in 2010 asked Dr. Lourdes Schnaas of the National Institute of Perinatology to design a screening test for child development evaluation (CDE) in its original version.¹³ This test would function as a tool for the timely detection of developmental problems in boys and girls from 1 month of life and up to one day before their fifth birthday, using a semaphore system of scoring: green (normal development), yellow (lag) or red (risk of delay) (Table 2).¹⁴

2. Validation process of a screening test

Once an instrument has been designed or identified that could be useful for meeting the objective of identifying in a timely manner the disease or phenomenon of interest, the evaluation of the validity seeks to answer the following questions:

- Does the scale appear to measure what it should measure? Does it reflect the structures of the domains of the phenomenon to be evaluated?

It is essential to answer the first question to establish the acceptability of the test in the application scenario, thereby establishing the *validity of appearance*.⁹ This validity depends on the analysis of the appearance of the test and their items as they seek to evaluate the phenomenon of interest (focus on interpersonal exchange, basic evidence, biological coherence of the components, attention to personal collaborations). The answer to the second question attempts to analyze the different components of the test to establish whether the instrument reflects the concept that it is intended to measure (important omissions, inappropriate inclusions, weight of components, satisfactory basic scales and the quality of the basic information) and with it establish *content validity*.

To answer these questions, a thorough analysis of the original version of the CDE test was conducted. Areas of opportunity were detected from which a modified version was developed.¹⁵ Precise scoring criteria and instructions were developed for each of the questions, the questions were reorganized in axes with common characteristics, the overall scoring criteria were modified for greater congruence and the modality observed was added in the items that were considered relevant. These modifications were carried out to adequately meet the requirements of appearance and content validity (Table 3).

Once the appearance and content validity were achieved, a *validation by consensus* was sought. To this end, a panel of

Table 2 General characteristics of the original version of the CDE test

Characteristic	Description
General organization of the test	14 different evaluation formats based on the age of the child
Age range (months)	1-59 months (in children born before 37 WG and who reached 2 years of age to calculate corrected age for selection of the questions for the corresponding age group)
Areas of development evaluated	Different developmental domains are evaluated (cognitive, personal-social, adaptative, motor and communication) grouped according to the following categories: gross motor, fine motor, language and social. In the evaluation of children >36 months, knowledge is added. Also includes questions about biological risk factors and warning signs.
Application modality of the items	Questions
Responses per item	Dichotomic: Yes/No
Item selection	The selection of responses to evaluate was made considering that >75% of children of that age already demonstrate the expected behavior and in a sequential manner in the different tests
Number of items per test	From 14 (1 month) to 36 (49-60 months)
Possible result	a) Normal development (green); b) Normal development with risk factors (yellow); c) Possible developmental delay; d) Probable developmental delay

CDE, Child Development Evaluation; WG, weeks of gestation.

experts was organized who analyzed each of the items of the CDE test, comparing the two versions of the test using a modified Delphi panel methodology. This panel arrived at the conclusion that the modified version of the CDE test was the most appropriate screening instrument for the assessment of children <5 years of age in the context of the country.¹⁶ In addition, it was established that the Battelle Developmental Inventory 2nd ed. in Spanish (BDI-2) was the most adequate instrument for diagnostic corroboration.¹⁷

- Does the test function similar to other validated instruments?

To answer this question, it is necessary that the tests be subjected to a *concurrent criterion process of validation*. This process seeks to determine the extent to which such test results coincide with diagnostic evaluations considered to be the gold standard or with those commonly used and considered as reference.¹⁸ For this, an appropriately designed study is required,¹⁹ considering the quality of the evaluation and the risk of bias.²⁰

A validation study allows establishing the ability of the test for the following characteristics: a) identify as abnormal those persons with the disease (sensitivity); b) identify as normal those persons without the disease (specificity); c) determine the percentage of the total persons who obtain a normal result in the screening test in which the disease is corroborated (positive predictive value); and d) determine the percentage of the total persons with normal results in the test who really do not have disease (negative predictive value). In the case of screening tests, it is recommended that they have values of sensitivity and specificity >70%.¹⁸

To determine the properties of the CDE test in its two versions (original and modified), validation studies of con-

current criteria²¹ were carried out against two instruments of evaluation of development considered as the reference standard: BDI-2¹⁷ and Bayley-III.²² As a secondary objective of this study the analysis of components evaluated was done (domains of development)²³ and for the differences by abnormal results (yellow vs. red).²⁴ According to the design of the study and with the results obtained and by a comparative analysis of the screening tests for problems in development designed and validated in Mexico, it was identified that the validation study of the CDE test had the least risk of bias in the data published.²⁵

Once the validity of the test is established, there are two additional questions to consider in order to contextualize the reliability of the results of the application in the field.

- In its field application, are there results similar to what has been described in the validation criteria?

Once the properties of the test have been identified in the validation study, it should be known if they are maintained in their application in the field. To determine this a study was carried out that included children from 16-59 months of age identified with risk of delay in the CDE test and in whom it was sought to establish diagnostic confirmation of delay through the application of the BDI-2. In this study it was found that 93.2% of the children identified with risk of delay according to the CDE test had diagnosis of delay in at least one domain evaluated by the diagnostic test.²⁶ This result was similar to that described in the study of validation criteria (93.8%),²¹ corroborating the reliability of the results when applying the test in the field.

- Does the scale function well when it is applied at different times or when it is applied by different persons?

Table 3 Characteristics of the original version of the CDE test and changes in the modified version

Characteristic	Component	CDE test	
		Original version ^a	Modified version ^b
<i>Purpose and framework</i>	Clinical function	<ul style="list-style-type: none"> - Qualitative characterization of the level of child development using a semaphore system - Able to identify changes in the level of development of children (through periodic evaluations) - Be the basis for the development of actions associated with the test results 	
	Justification	<ul style="list-style-type: none"> - Establish the calculation of corrected age, which reduces false positives by inadequate age - Evaluate all domains of child development - Include, in addition, medical characteristics that can cause the problem and require different management (head circumference, abnormal movements) 	<ul style="list-style-type: none"> - Different from the original version (interrogation only) includes questions that can be observed, which makes it more objective - Questions in five axes are restructured for ease in understanding and rating - Specific application instructions were developed and qualification criteria for each response - All tests are concentrated in one manual application, avoiding an uncontrolled supply in 14 different formats
	Applicability	The objective of the test is to apply to all children <5 years of age in Mexico	
<i>Comprehensibility</i>	Simplicity	<ul style="list-style-type: none"> - All responses are dichotomic (Yes/No) - All areas of development are qualified equally 	<ul style="list-style-type: none"> - Qualification criteria were simplified
	Oligovariability	<ul style="list-style-type: none"> - One area of development is evaluated using two or three questions, whereas for the corresponding domain in the diagnostic test there are at least three times more questions 	
	Transparency	<ul style="list-style-type: none"> - The area of warning signs is confusing because for some, one results in red, whereas for other questions it is two or more 	<ul style="list-style-type: none"> - Warning sign questions were distributed in three axes; those questions related to the neurological examination were separated in an independent axis; one that becomes a red alarm sign; the others as alert signs
	Biological connotation	<ul style="list-style-type: none"> - The original version adds head circumference <10th percentile or >90th percentile. With this, 20% of the population obtained an abnormal test result without having problems 	These criteria were modified to be ± 2 SD

Table 3 (cont.)

Characteristic	Component	CDE test	
		Original version ^a	Modified version ^b
<i>Replicability</i>	Clarity of instructions	No instructions for administration of the test items	A manual was developed where the form of application and interpretation of the test items were completely explained
	Unbiased evaluation	This version provides only interrogation as a source for obtaining information, which gives a bias to both the interpretation and the response of the caregiver	- Two modalities of administration were established: questioning and observation
<i>Appropriateness of the measurement scale</i>	Comprehensibility	- All categories have exhaustive, mutually exclusive, and fully inclusive options and with actual values options	
	Discrimination	- When included in qualifying the biological risk factors constant for all ages, it is not possible to assess changes in the status of the same person	- The rating system is adjusted so that biological risk factors as well as warning signs do not change the overall test results
<i>Validity of appearance</i>	Focus on interpersonal interchange	- The fact that it is only a questionnaire is a limitation on the quality of the information obtained	- Corroboration of those aspects through observation of carrying out the type of behavior allows more objectivity and accuracy
	Focus on basic evidence	- Questions for each age group are in accordance with what the child should be carrying out in that period	
	Biological coherence of the components	- Items are grouped into categories that allow an assessment of similar aspects in the same area, in addition to carrying out a progressive sequence in complexity during the test duration	
	Attention on personal relationships	- Based on the understanding and cooperation of the mother or caregiver	- Criteria for evaluating behavior and <i>tips</i> are established to promote the evaluation
<i>Content validity</i>	Important omissions	- Unlike other screening tests, it is the only one that includes aspects of neurological examination, which may be the cause of the problems and the identification of which favors timely care	
	Inappropriate inclusions	- In questions about head circumference, a wide range of results were included	- Cut-off was established for considering abnormal head circumference
	Weight of the components	- In the same category (alert signs), items with only one are modified in the results, others with two, etc.	- Items with similar eligibility criteria are grouped in separate axes
	Satisfactory elemental scales	- Criteria for each test item were not stipulated	- Clear criteria were established for each item response

Table 3 (cont.)

Characteristic	Component	CDE test	
		Original version ^a	Modified version ^b
Ease of use	Quality of the basic information	<ul style="list-style-type: none"> - The instructions are very general and the processes required to correctly apply the test are not explained in detail (corrected age calculation and measurement of head circumference) 	<ul style="list-style-type: none"> - Instructions for the evaluation of each item are specified and the complicated processes are explained in detail (calculation of corrected age and head circumference measurement)
		<ul style="list-style-type: none"> - The test was designed to be used in 14 independent formats, complicating the supply of each one 	<ul style="list-style-type: none"> - 14 formats are grouped in the same manual available also through tabs, to evaluate the test items - Easy application and can be applied by persons with a low level of education - Formats of application are found in a manual; only requiring reproduction of the answer page to be placed in the file - Application materials can be assembled using locally available resources

CDE, Child Development Evaluation; SD, standard deviation.

^aRizzoli-Córdoba et al. (Ref. 21); ^bRizzoli-Córdoba et al. (Ref. 15).

If a patient is evaluated at the same time by two different evaluators, the results of the evaluation should be similar; this is what is measured by the *inter-evaluator reliability*. Concordance in the result of the test when the same patient is evaluated on different occasions in a short time frame is referred to as *test-retest reliability*. In a study with the objective of evaluating a model of supervision that would allow identifying the quality of the application of the CDE test at the populational level, an inter-evaluator concordance of 86.1% was found through the simultaneous application of the test as a shadow study, and a concordance in the re-application of the test between the supervisor and the person administering the test of 88.1%. These differences in the results were associated with the incorrect administration of some of the items by specific personnel, reinforcing the need of accompanying and verification of the correct application in the field in order to obtain reliable results.²⁷

For the timely detection of problems in the CDE, the following should be proposed as a first line: a) screening tests that appear to measure what they should measure (validity of appearance); b) include all developmental domains to be evaluated (construct validity) that when compared with diagnostic evaluations considered to be the *gold standard* have values of specificity (total percentage of persons with normal development by the gold standard which the screening test identifies as normal) >70% (validity of criteria);¹⁸ c) have similar results when given at different times or by dif-

ferent persons (test-retest or evaluator reliability) given that childhood development is a process of change; d) detect these differences with the passage of time (sensitivity to change); and e) be quick and easy to administer so that they can be used by nonspecialized personnel in primary care units (usefulness).²⁸

The evidence available on the CDE test confirms the compliance of each of the above-mentioned points, for which it is currently considered to be most appropriate test for timely detection of developmental problems in Mexico¹⁶ and is the test recommended by the National Center of Childhood and Adolescence for evaluation of childhood development in primary care units in the country.²⁹ The analysis of the information obtained through its field application will allow for identification of areas of opportunities and to confirm if the results of the different validation steps are consistent when applied as part of a public policy.

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Conflict of interest

The authors declare that they have no conflicts of interest.

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